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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,415	01/16/2004	William S. Brusilow	2930-109	5654

6449 7590 08/05/2010

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ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
08/05/2010	ELECTRONIC

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/758,415
Filing Date: January 16, 2004
Appellant(s): BRUSILOW, WILLIAM S.

Monica Chin Kitts
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/18/2010 appealing from the Office action mailed 2/18/2010.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The Examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Brain Research Bulletin	Apostolakis	9-1988
Pharmacoloqy Biochemistry	Ginefri-Gayet et al.	1992

and Behavior

20030013650 A1	Liedtke et al.	1-2003
20020173537 A1	Feurerstein	11-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5, 10-11, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Apostolakis et al., Brain Research Bulletin, or Ginefri-Gayet et al., Pharmacology Biochemistry and Behavior, in view of Liedtke et al. (US Pub. No. 20030013650 A1), and further in view of Feurerstein et al. (US Pub. No. 20020173537 A1).

Apostolakis teaches methionine sulfoximine (MSO) is a centrally acting neurotoxin with convulsive properties; it has been used in study of epilepsy. MSO suppresses the formation of glutamine (see page 257, col. 1, first paragraph). Apostolakis further teaches pharmaceutical unit doses in an amount of methionine sulfoxime of 2 mg/ml normal saline and 200 micro gram/100 micro liter administered intravenously (IV) and intracerebroventricularly (IVT). The animals were sacrificed at different times after MSO administration (see page 257, column 2).

Ginefri-Gayet teaches pharmaceutical unit doses in an amount of methionine sulfoxime of 50-75 micro gram/10 micro liters. See page 174, column 2, under ICV Injection of MSO.

Liedtke teaches that the present invention relates to the identification in vertebrate animals including humans, of an ion channel for rapid conduction of cations,

among them, Ca^{2+}. This ion channel, named VR-OAC, demonstrates activity as an osmoreceptor, and also demonstrates a role in mechanical stimulation and responsiveness (see page 1, paragraph 2). VR-OAC is expressed in nerve-cells of the hippocampus, CAl region, a region of importance for memory and in epileptic seizures (page 6, paragraph 89). Liedtke further teaches that the recombinant protein can be refolded prior to or after cleavage to form a functionally active polypeptide. Suitable redox (reducing/oxidizing) agent pairs include, but are not limited to, reduced glutathione/glutathione disulfide, cystine/cysteine, cystamine/cysteamine (see page 16, paragraph 203). Mammalian expression vectors contemplated for use in the invention include vectors with inducible promoters, such as, a glutamine synthetase/methionine sulfoximine co-amplification vector, (see page16, paragraph 207), which reads on claims 10 and 11.

Feurerstein et al. teach of a compound treating neurodegenerative diseases including polyglutamine diseases (see page 1, paragraph 0003). The composition is useful for treating a polyglutamine disease e.g. Huntington's disease, dentorubropallidoluysian atrophy, spinal and bulbar muscular atrophy, spinocerebellar ataxis (SPA -1, -2, -3, -6, -7), and acute and chronic glaucoma. Also the compounds are useful for treating disorders of central nervous system e.g. stroke, hypoglycemia, hypoxia, trauma, epilepsy, Alzheimer's disease, AIDS-associated dementia, amyotrophic lateral sclerosis, Parkinson's disease and chronic alcoholism (see page 2, paragraph 0030).

Clearly, the skilled artisan is provided with ample instruction and motivation to

use MSO in the treatment of neurodegenerative diseases including polyglutamine diseases. The skilled artisan is motivated to make compositions of the well known ingredients used in applications for treatment of polyglutamine diseases. The prior art teach of the same component and its concentration that is instantly claimed. Accordingly, it is well settled that products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure that is used to treat one disease, therefore will treat another disease from the same family as taught by Feurerstein et al., the properties applicant discloses and/or claims are necessarily present. In other words, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. See In reBest, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach and suggest the invention as claimed. Thus the claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.

Thus in the absence of evidence to the contrary, the invention of claims 1-5, 10-11, and 21 would have been prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made.

(10) Response to Argument

Appellant argues that the present claims are directed to a method for treating a polyglutamine disease which is not disclosed or suggested by the cited prior art individually or in combination. The composition and kit claims were withdrawn from consideration in view of appellant's election of group I for examination in the present application and are not involved in this appeal. In summary, Appellants contend that Liedtke and Feurerstein do not suggest or disclose the therapeutic use of MSO and Apostolakis and Ginefri-Gayet actually teach away from using MSO as a treatment for polyglutamine diseases as in the present invention. In view of the numerous undesired effects caused by MSO (convulsant, neurotoxin, etc.) discussed in the cited prior art, appellants contend that the combination of cited prior art does not suggest or disclose administering MSO to any patients for any therapeutic purposes. Therefore, appellants contend that the combination of cited references does not suggest or disclose a method for treating a polyglutamine disease, comprising administering a compound selected from the group consisting of L- methionine S-sulfoximine, L-ethionine S-sulfoximine, glufosinate and branched chain a- keto acids derived from leucine, isoleucine or valine as in the present claims.

Examiner does not agree. Appellant's arguments are not persuasive, all mentioned references are relevant to polyglutamine disease and administration of MSO, please see the rejection under 35 USC 103(a). The primary reference Apostolakis et al. very clearly teach the administration of MSO for the suppression of glutamine. Appellant discusses that the prior art teaches away from using MSO and further Appellant

mentions the numerous undesired effects caused by MSO. However, if MSO administration causes undesired effects, it will necessarily cause the same undesired effects in Appellant's treatment of poly glutamine disease, since the characteristics and properties of compounds are not separable from each other. MSO used for the same treatment will produce the same undesired effects in both compositions, the Appellant's and the prior art. However, the prior art teaches that at lower concentration there has been some benefit of using MSO. Appellant's attention is directed to the result section where it is reported that 2 out of 14 animals that received MSO recovered fully. Appellant has not indicated the toxicity level of MSO that can be used. If according to the specification of the instant application on page 8 where it indicates MSO can be administered at a dose of about 2.0-10.0 mg/kg and 10 mg/kg being the upper limit therefore this teaching is rendered obvious by the prior art Apostolakis et al. since this teaching overlaps with the teaching of the prior art. Apostolakis et al. teach intravenous administration of 3 to 9 mg/kg of MSO, see page 257, method. Therefore, any undesired effect from administration of MSO seen by the prior art very clearly is present with Appellant's. Very clearly, the teachings of the prior art references render the claimed invention obvious and was within the ordinary skill in the art to make and use at the time the claimed invention was made. Appellant's arguments and remarks have been carefully considered in their entirety, but fail to be persuasive in establishing error in the propriety of the present rejection.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Zohreh Vakili/

Patent Examiner, Art Unit 1614

Conferees:

/Ardin Marschel/

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